havior and menstrual symptoms dimensions were excluded because of conceptual issues. In the future, they will be presented as optional modules. The analyses identified a new structural model applicable to pre, peri and postmenopausal women. The new WHQ is made of a 23-item core questionnaire which investigates 6 domains: anxiety/depressed mood, well-being, somatic symptoms, memory/concentration, vasomotor symptoms, and sleep problems. The cross-sectional psychometric properties of the 23-item WHQ in each country were good and found to be better than those obtained using the 37-item version. **CONCLUSIONS:** At this stage, the 23-item WHQ can be used in international trials to assess the impact of condition, disease or treatment on emotional and physical well-being of women. Its reproducibility and responsiveness to change over time need to be documented.

PMT9

ASSESSING THE COST-EFFECTIVENESS RATIO OF A NEW ANTI-PLATELET AGENT: METHODOLOGIC ISSUES

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In a large Phase III double-blind randomised clinical trial, the CAPRIE study (clopidogrel versus aspirin in Patients at Risk of Ischemic Events), two anti-platelet agents were compared in secondary prevention of ischemic events (myocardial infarction, ischemic stroke, vascular death) in atherothrombotic patients. The study was not designed to collect health economic parameters. **OBJECTIVES:** we needed to assess the incremental cost-effectiveness ratio of the new anti-platelet agent in the main European countries and to test various hypotheses. **METHODS:** *Clinical outcomes*: A Markov model designed with several clinical states combined the rates of all ischemic events (fatal and non fatal, primary and subsequent) reported in the CAPRIE study. The rates of adverse events were also taken into account. *Survival data:* the remaining life expectancy of the patients who experienced an event was not directly estimated from the CAPRIE study as the mean follow-up of the patients was only two years. The survival estimates was approached by identifying, in the Framingham study, cohorts of patients similar to the CAPRIE patients. *Resources use and costs:* decision trees about inpatient and outpatient management of myocardial infarctions and ischemic strokes were built from available data (literature, data base, expert opinion) and were locally validated. **RESULTS:** The economic model allowed to calculate the incremental cost-effectiveness ratio of the new anti-platelet agent for the basic scenario (CAPRIE study) and for other scenarios (changes of the time horizon, considering that the comparator could not be the reference treatment for all the patients in a real life situation, high risk patients analysis). **CONCLUSION:** Because they are protocol driven, the Phase III double-blind randomised clinical trials do not usually reflect what would happen in the real life. Modeling, which allows to perform simulations, could be a way of correcting.

PMT10

MODELLING ISSUES: FIRST EPISODE SCHIZOPHRENIA

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BACKGROUND: The development of an economic model to assess antipsychotics for first episode schizophrenia raised several issues: (i) clinical and economic evidence relates to chronic schizophrenia; (ii) inconsistent reporting of outcomes and adverse events; (iii) comparison of costs and outcomes across several interventions is complicated by (a) an absence of head to head comparisons (b) intolerance or resistance to 3 plus antipsychotics. **OBJECTIVES:** To design a decision analytic model to evaluate the relative efficiency of antipsychotics. **METHODS:** Two composite variables were defined to incorporate 23 efficacy and safety events: (i) acceptable treatment (able/willing to continue allocated therapy, with/without side effects or symptom control) (ii) unacceptable treatment (unacceptable side effects or symptom control, non compliance). Utility values were defined for each variable. Clinical data were extracted from systematic reviews separately for first episode and chronic schizophrenia. Age specific resource use data were estimated from national statistics to proxy first episode patients. Follow on therapy for people failing first therapy was estimated by (i) specifying drug sequence; (ii) treating follow on therapy as a random event. Monte Carlo simulation analysis was used to reduce complexity and incorporate uncertainty. **RESULTS:** It was not possible to identify consistent data for first episode patients only. Interpretation of the specific treatment sequences was complex with 32 possible combinations identified. There were substantial differences within classes of antipsychotics. The results were sensitive to: (i) specification of follow on therapy (ii) distributional form applied to data. **CONCLUSIONS:** The analysis highlighted the poor quality and absence of relevant data. This could not be dealt with by modelling. Current classifications of typical and atypical antipsychotics may not be relevant.

PMT11

METHODOLOGY FOR IDENTIFYING PATIENTS AT HIGH RISK FOR OSTEOPOROTIC FRACTURES WITHIN A MANAGED CARE ENVIRONMENT

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Osteoporosis is a major public health problem becoming increasingly important as our population ages. Approximately one in two women will experience an osteoporotic fracture in their lifetime. Additionally, millions have low bone mass that increases fracture risk. **OBJECTIVE:** To develop a methodology, in a managed care environment, that identifies members at high-risk for osteoporotic fractures. **METHODS:** This was a retrospective database study. The study population was from a Midwest health plan of 1.38 million lives. The database consisted of all pharmaceutical, professional, and institutional claims linked at the patient level. The study population was identified by the following criteria: continuously enrolled from 7/1/95 to 3/31/99, complete coverage, individuals older than age 45 for women and age 65 for men with fracture of interest, specific fracture by site; hip (820.0 to 821.39), vertebrae (806 to 806.91), and forearm (813.0 to 813.9x), past history of fracture and specific site by V codes (13.5 and 15.5), chronic users of steroids (⩾180 days exposure over a period of 24 months), history of transplant (by CPT-4 and V codes), a diagnosis code of 733.0x, current history (in study period) of ICD-9 codes for pathologic fractures 733.1 to 733.19, a family history of musculoskeletal disease (V code 17.8), and individuals with bone density studies (by CPT-4 codes). **RESULTS:** Over 120 million claims were screened to stratify the population (prior to 1997) into risk bands. We used 2,000 patients with current osteoporotic fractures to develop and to verify a predictive model of fracture risk. **CONCLUSIONS:** A claims based model identified high-risk patients for fractures. Application of the model to 1999 data generated a list of patients for intervention.

PMT12

DATA REQUIREMENTS OF SECOND-GENERATION ECONOMIC MODELS IN HIV/AIDS

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Economic models for highly active antiretroviral (HAART) drug regimens used in HIV infection differ from other models in that they must accommodate the results of short trials, but yield relatively long-reaching predictions of health outcomes, resource use, and costs, in an environment where valid epidemiologic data are scarce. Standard Markov models were effective for short survival times. With improved treatment options, survival of HIV patients has been prolonged significantly. A methodological consequence is that Markov models with fixed transition probabilities may no longer be reliable. Furthermore, the number and disparity of outcomes of interest, such as surrogate marker changes, primary health outcomes, treatment side effects, degree of adherence, and viral resistance to subsequent regimens complicate Markov approaches. **OBJECTIVE:** To compare two possible solutions:1) a system of linked, staged Markov models; and 2) a hierarchical Monte Carlo simulation. **METHODS:** Application of both methods to existing data. **FINDINGS:** The data requirement for the staged Markov system depends on whether transitions are derived empirically or from theory. We found that approximately 27 exposure years are required per health state to ensure stable incidence densities, and that 12 model states health states can capture both risk of progression and risk of events observed in about 1500 patients over 3 years, but that stable transition rates require at least 50 exposure years per health state, and vary by antiretroviral experience. The hierarchical Monte Carlo model has more modest requirements for data density, but depends on long streams of uninterrupted observations from unique patients. The strengths and weaknesses of these two approaches will be illustrated with data from the ritonavir and ABT378 trials.

PMT13

TRANSFERING THE RESULTS FROM ECONOMIC EVALUATIONS: THE USE OF BASILIXIMAB IN TRANSPLANT PATIENTS

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Within pharmacoeconomic analysis, the generalizability of results from one jurisdiction to another should not be presumed. In general re-analysis of data for specific jurisdictions is required. Thus, the lack of transparency in the reporting of evaluations can limit their applicability to decision-making. **OBJECTIVES:** First, to build a decision analytic model to replicate the results from a stochastic analysis of a US trial based economic analysis. Second, to assess the transferability and generalizability of results to the Canadian setting. **METHODS:** A decision analysis model was developed to replicate results from the US trial comparing the use of basiliximab and cyclosporin to placebo and cyclosporin for renal transplant patients. We determined the necessary parameters required to replicate the study results and conducted re-analysis for the Canadian setting. Data required related to clinical probabilities, costs of treatments and treatment paths. **RESULTS:** Results from the US study were replicated using the decision analytic model. The cyclosporin-basiliximab arm led to the least cost path when compared to cyclosporin-placebo, with costs of $28,858 and $32,253 respectively, approximating the results of the stochastic analysis of $28,927 and $32,300. Further analysis was conducted for the Canadian setting, and found similar results. **CONCLUSIONS:** Where the criteria for geographic transferability are satisfied it is possible to transfer the results of a clinical trial to other geographic locations. However, it need not follow that results are generalizable. In addition, when assessing the generalizability of